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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/431,451	11/01/99	SENAPATHY P	34623.005

HM12/0313

INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER	
SISSON, B	

ART UNIT	PAPER NUMBER
1655	6

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/431,451	SENAPATHY, PERIANNAN	
	Examiner	Art Unit	
	Bradley L. Sisson	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 November 1999* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Drawings

1. The drawings remain objected to for reasons of record; see the PTO-948 that was attached to Paper No. 3. Acknowledgement is made of applicant's willingness to file corrected drawings upon notification of allowable subject matter.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See the prior Office action for the basis of the rejection.

Response to argument

At page 6, bridging to page 7 of the response of 24 January 2001 argument is advanced that the Office has not made a proper rejection. Attention is directed to the aspect of there being a requirement of "undue" experimentation, not simply the need to conduct experimentation.

Then above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. As set forth on pages 6-7 of the prior Office action,

attention was directed to the decision in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the again reproduced text:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (emphasis added)

As set forth in the prior Office action, the specification of the subject application has not set forth the starting materials and more particularly, the reaction conditions. While inference has been found as to there being prior art methods, the specification has not set forth the specific manner

by which the prior art methods are to be modified so to arrive at a non-obvious invention. As set forth in the prior Wands analysis, the specification has not provided any working examples and the guidance provided is prophetic and of a general nature. Such general intimations do not rise to the level of an enabling disclosure.

At page 9 of the response it is asserted that "nothing more [than the mere reference to prior art methods] is needed to practice the invention as broadly as it is claimed." This argument has been fully considered and has not bee found persuasive towards the withdrawal of the rejection. Such statements appear to be a straight forward assertion that one of skill in the art could resolve any and all operating parameters without the need for even the first example or even any starting materials or reaction conditions, *specific for the claimed invention*, being set forth within the four corners of the subject application. This argument, as shown above in the decision of *Genentech*, is well settled. To rely upon the public to resolve how a claimed method is to be practiced places an undue burden upon the public.

4. At pages 9-12 of the Response attention is directed to a Rule 132 declaration filed in another application (Serial Number not provided). A careful review of the contents of the subject application fail to locate the aforementioned declaration and as such, an analysis of the arguments and assertions provided by both applicant's representative and declarant cannot be made.

5. Affidavits or declarations, such as those under 37 CFR 1.131 and 37 CFR 1.132, filed during prosecution of another application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make

the remarks of record in the later application and include a copy of the original affidavit or declaration filed in the parent application.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1-29 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the original specification. In the specification, applicant has stated that

a. "the present invention is able to amplify specifically a majority of exons from most genes from a whole genomic sample" (page 3, lines 13-15);

b. "[t]he invention is also drawn to a method of specifically amplifying the flanking regions of exons from a sample containing genomic DNA" (page 13, lines 5-6); and

c. "a still further embodiment of the invention is drawn to a method of specifically amplifying regions flanking consensus sequence in a sample of nucleic acid of totally or partially known sequence" (page 13, lines 18-20),

and these statements indicate that the invention is different from what is defined in the claim(s) because the now claimed method is no longer drawn to any method that requires the "specific" amplification of any target sequence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
March 12, 2001